REMARKS

Claim 1 is amended. Claims 1-13 and 18-23 are pending in the application. Support for the amendments can be found at least at paragraphs 58, 86, 90 and figure 1of the specification in U.S. Pub. 2007/0259008A1. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Claim Rejections Under 35 USC § 103

Claims 1-13 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. and Cammas, et al. Applicantss respectfully traverse this rejection.

Claim 1, as amended, is as follows:

> A drug delivery molecule comprising:
> a polymerized carboxylic acid molecular scaffold having a plurality of free carboxylic acid groups;
> a plurality of biologically active molecular modules, each being covalently linked to the same polymerized carboxylic acid molecular scaffold, wherein said active modules comprise: at least one targeting module for promoting cellular uptake by a target cell; and
> at least one pro-drug module for altering cellular metabolism of the target cell;
> wherein at least one active module comprises a polypeptide and/or polynucleotide; and wherein the scaffold is a homopolymer.

Applicants respectfully submits that LaFleur fails to disclose or teach at least the following, as set forth by claim 1: (a) a drug delivery molecule and (b) a plurality of biologically active molecular modules (i.e., targeting and prodrug modules) that are covalently linked to a same polymerized carboxylic acid molecular scaffold. Instead, LaFleur discloses KDI compositions that are formulated in a biodegradable, polymeric drug delivery system (col. 151, ll. 49-50). LaFleur further discloses that the KDI compositions are formulated for example, as described in at least U.S. Pat. No. 5,340,849 (col. 151, ll. 49-52). '849 discloses the use of a thermoplastic system that provides a drug-delivery system, where a polymer solution containing a bioactive agent is administered (col. 6, ll. 34-38). In this system, the polymer solidifies and

entraps or encases the drug within the polymer matrix ('849, col. 6, ll. 45-46).

LaFleur also discloses that antibodies may be conjugated to other compositions (col. 72, ll. 17-23) and further defines these compositions as being those that comprise KDI polypeptides (col. Ll. 25-50). As such, La Fleur does not teach to conjugate an antibody to a polymerized carboxylic acid molecular scaffold for drug delivery.

Cammas is not seen to remedy the defects of LaFleur and is cited for its relevance regarding the use of polymers of malic acid in biocompatible hydrolyzable devices. Cammas exemplifies the application of PHAs in the biomedical field, which includes the use degradable micelles, nanoparticles, etc. (p. 274, col. 1, para. 3). Cammas further indicates that biologically active molecules can be entrapped, dissolved or encapsulated by nanoparticles made from poly(β-malic acid benzyl esters) (p. 276, last para. through p. 277 first para.). Cammas concludes that PMLA polyesters can be used to prepare materials or additives for temporary use in drug delivery systems (p. 282, conclusion).

The Office Action (p. 5 of Office Action dated 1/14/09) suggests that Cammas teaches polymaic acid polymers having biologically active molecules as pendant groups and thus, it would have been obvious to one skilled in the art to use the polymer of Cammas to conjugate the targeting, prodrug, pore-forming, PEG, and reporter moities of LaFleur.

Applicants's respectfully submit that Cammas only discloses the use of micelles as drug carriers (p. 275, col. 2, last para.) and uses nanoparticles to test drug loading capacity (p.279, col. 2, first full para.). As indicated above, Cammas discloses biologically molecules that are entrapped, dissolved or encapsulated by nanoparticles and not covalently linked to a same polymerized carboxylic acid molecular scaffold, as set forth by the claims. Since both LaFluer and Cammas disclose the use of polymeric drug systems that encapsulates or entraps biologically active molecules, one of skill in the art would not have been motivated to combine the teachings to conjugate targeting and prodrugs to a polymerized carboxylic acid molecular scaffold to form a drug delivery molecule.

For at least the aforementioned reasons, LaFleur in view of Cammas does not render obvious present claim 1. Likewise, dependent claims 2-13 and 20 are also patentable for at least the same reasons. In view of the foregoing, Applicantss respectfully request that the Office withdraw the rejection.

Claims 1-13 and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. and Cammas, et al., and further in view of Saito, et al. Applicantss respectfully traverse this rejection.

Claims 1-13 and 20 are patentable over LaFleur and Cammas for at least the same reasons discussed above. Claims 18-19 depend from claim 1, and as such includes all the limitations thereof, and is therefore patentable over LaFleur and Cammas for at least the same reasons discussed above with regard to claim 1.

Saito is not seen to remedy the defects of LaFleur and Cammas and is cited for its relevance regarding the use of cleavable disulfide linkages. As such, the combined teachings of the prior art fail to teach or suggest each element of the claimed invention. Thus, the combination suggested by the Office cannot render the claimed invention obvious. In view of the foregoing, Applicantss respectfully request that the Office withdraw the rejection.

Claims 1-13 and 20-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. and Cammas, et al., and further in view of Summerton, et al. Applicantss respectfully traverse this rejection.

Claim 21 depends from claim 1, and as such includes all the limitations thereof, and is therefore patentable over LaFleur and Cammas for at least the same reasons discussed above with regard to claim 1.

Summerton is not seen to remedy the defects of LaFleur and Cammas and is cited for its relevance regarding the use of the antisense molecule morpholino. As such, the combined teachings of the prior art fail to teach or suggest each element of the claimed invention. Thus, the combination suggested by the Office cannot render the claimed invention obvious. In view of the foregoing, Applicantss respectfully request that the Office withdraw the rejection.

Claims 1-13 and 20-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. and Cammas, et al., and further in view of Khazenzon, et al. Applicantss respectfully traverse this rejection.

Claims 22-23 depend from claim 1, and as such includes all the limitations thereof, and is therefore patentable over LaFleur and Cammas for at least the same reasons discussed above with regard to claim 1.

Khazenzon is not seen to remedy the defects of LaFleur and Cammas and is cited for its relevance regarding the use of the antisense molecule targets of α4 laminin. As such, the combined teachings of the prior art fail to teach or suggest each element of the claimed invention. Thus, the combination suggested by the Office cannot render the claimed invention obvious. In view of the foregoing, Applicantss respectfully request that the Office withdraw the rejection.

Claim Rejections Under 35 USC § 102

Claims 1 and 18-20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bulmus, et al. Applicants respectfully traverses this rejection.

Applicants respectfully submits that Bulmus, fails to disclose or teach at least a scaffold that is a homopolymer, as set forth by claim 1. Instead, Bulmus discloses a teropolymer that may be used to deliver biomolecular drugs (abstract, p. 106, col. 1, last para. & col. 2, second para.). The teropolymer of Bulmus comprises a backbone of methacrylic acid, butly acrylate and pyridly disulfate acrylate units (p. 111, col. 2, third para. and fig. 1) and was designed to create a glutathione-reactive and pH-sensitive, membrane disruptive polymer (p. 106, col. 2). As such Bulmus does not teach or suggest the drug delivery molecule of the present invention.

For at least the aforementioned reasons, Bulmus does not anticipate present claim 1. Likewise, dependent claims 18-20 are also patentable for at least the same reasons. In view of the foregoing, Applicantss respectfully request that the Office withdraw the rejection.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned at the Los Angeles, California telephone number (213) 633-6800 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50670.

Respectfully submitted,
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